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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,384	04/01/2004	Eilaz Babaev	103514-0011-103	7585

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EXAMINER	
CHENG, JACQUELINE	
ART UNIT	**PAPER NUMBER**
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,384	BABAEV, EILAZ	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 37-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 37-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/12/04 10/4/04 4/1/04 11/6/06 6/5/06 2/6/06.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1, 7, 9-11, 15-17, 37, 40-42, 47, 48, 50, 53-55, 60, 61** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 4, 5, 7, 8, 13, 14, 16-18 and 21 of U.S. Patent No. 6,478,754 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 13 and 21 in the patent claim substantially the same thing as claims **1, 37, 50, and 63** in the application of an method and apparatus of applying medicament to a tissue and delivering ultrasonic energy from a distance at an intensity to penetrate the wound tissue to a beneficial depth to prove therapeutic effect to the tissue. The spray of the liquid is also provided from a transducer having a distal

radiation surface. As to the dependent claims, they are rejected as (patent claims to application claims) 2, 14 to **9-11, 40-42, 53-55** | 4, 16 to **16, 47, 60** | 5, 17 to **15** | 7 to **48, 61** | 8, 18 to **17.**

3. **Claims 1, 9-11, 15-17, 37, 40-42, 47, 48, 50, 53-55, 60, 61** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2-5, 7-10, 12, 13, 16, 17 and 20 of U.S. Patent No. 6,569,099 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 9, and 16 in the patent claim substantially the same thing as claims **1, 37, 50, and 63** in the application of an method and apparatus of applying medicament to a tissue and delivering ultrasonic energy from a distance at an intensity to penetrate the wound tissue to a beneficial depth to prove therapeutic effect to the tissue. The spray of the liquid is also provided from a transducer having a distal radiation surface. As to the dependent claims, they are rejected as (patent claims to application claims) 2, 10, 17 to **9-11, 40-42, 53-55** | 4, 12 to **16, 47, 60** | 5, 13, 19 to **15** | 7 to **48, 61** | 8, 20 to **17.**

4. **Claims 1, 9-11, 15-17, 37, 40-42, 47, 48, 50, 53-55, 60, 61** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 4, 5, 7, 8, 13, 14, 16-18 and 21 of U.S. Patent No. 6,663,554 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 13, and 21 in the patent claim substantially the same thing as claims **1, 37, 50, and 63** in the application of an method and apparatus of applying medicament to a tissue and delivering ultrasonic energy from a distance at an intensity to penetrate the wound tissue to a beneficial depth to prove therapeutic effect to the tissue. The spray of the liquid is also provided from a transducer having a distal

radiation surface. As to the dependent claims, they are rejected as (patent claims to application claims) 2, 14 to **9-11, 40-42, 53-55** | 4, 16 to **16, 47, 60** | 5, 17 to **15** | 7 to **48, 61** | 8, 18 to **17.**

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-4, 7, 9-11, 15, 16, and 63** are rejected under 35 U.S.C. 102(b) as being anticipated by Gerasimenk (SU 1106485). Gerasimenk discloses delivering ultrasonic energy of a frequency range of around 26.5 kHz from a non-contact distance of about 3-10 mm from the wound surface. A medicinal solution, such as an antiseptic solution, is sprayed onto the wound surface and is subjected to the action of the ultrasound, sonicating the medicament. The ultrasound and the medicament is applied to reduce the time required to treat the wounds, which helps to heal the wound (providing a therapeutic effect), decreasing the time the wounds takes to heal (abstract).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section.102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 37-42, 47, 49-55, 60, 62, 66** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk in view of Anthony (US 4,679,551). Gerasimenk discloses all of claim 17 as disclosed above except for introducing the liquid to be sprayed to the distal radiation surface of the ultrasonic transducer from a reservoir. To introduce liquid to be sprayed to the distal radiation surface of the ultrasonic transducer is not unknown in the art. Anthony discloses just such a device. In Anthony a device for performing therapeutic treatments is an ultrasound sprayer that introduces a liquid such as water (a non-medicament) from a connected reservoir such as a tank (abstract). It would be obvious to modify Gerasimenk to spray the medicament from the distal radiation surface such as in Anthony, if it does not already provide the medicament as such.

9. **Claims 6 and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk. Gerasimenk is not clear on whether the medicinal solution is applied before applying the ultrasound, or during application of the ultrasound. Either method is capable as the medicinal solution can be sprayed first, and then the ultrasound delivered, also the aerosol spray can be subjected to the ultrasound waves while it is being sprayed.

10. Gerasimenk also does not explicitly disclose that the procedure is repeated, but it is obvious to one skilled in the art at the time of the invention to provide a series of the same 1-5 minute treatment to further reduce the time required to treat infected wounds.

11. **Claims 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk in view of Duarte (US 6,273,864 B1). Gerasimenk does not explicitly disclose how the ultrasonic

application reduces the time required to treat infected wounds, but it is well known in the art that providing ultrasonic waves in the frequency ranged of 26 kHz decreases healing time by stimulating regeneration of cells as disclosed by Duarte (col. 6, line 35-44).

12. **Claims 5, 8, 64 and 65** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk in view of Martin (US Patent No. 6,500,133).

13. **Claims 43-46 and 58-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk in view of Anthony further in view of Martin.

14. Martin et al. discloses a medical instrument that uses ultrasonic energy for various medical applications. It is obvious that in order to apply Gerasimenk and provide ultrasonic therapeutic energy to a wound, the energy must have a particular amplitude, frequency, radiation surface area and perimeter that is capable of achieving the therapeutic effect. These surfaces and perimeters can be of various shapes and sizes as the abstract and col. 3, line 8-10 of Martin et al. discloses. Martin et al. also specifically discloses using a concave as well as a convex geometry (col. 3, line 19-35) as shapes for the radiation surface. Athough Gerasimenk discloses a preferred frequency and amplitude range, it would be obvious to one skilled in the art to change these parameters in order to possibly further the utility of Gerasimenk to achieve the best therapeutic effect on the wound.

15. **Claims 48 and 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerasimenk in view of Anthony further in view of March (US 6,200,259 B1). Neither Gerasimenk nor Anthony explicitly disclose using any particular waveform for the ultrasonic

frequency but it would be obvious to one skilled in the art to use any waveform that would provide the desired therapeutic effect. Kaufman discloses an ultrasonic therapy apparatus and method in which the ultrasonic energy frequency is modulated by a sinusoidal signal (abstract) showing that to use a sinusoidal signal is well known in the art to provide therapy to tissue. \

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Soring (US 6,916,296 B2).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER

JC